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A successful approach to minimizing attrition in racial/ethnic minority, low-income populations



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ABSTRACT

Background: Recruiting and retaining minority participants in clinical trials continue to be major challenges. Although multiple studies document lower minority trial enrollment, much less is known about effective minority retention strategies. Our objectives were to evaluate an innovative approach to high RCT retention of minority children, and identify child/caregiver characteristics predicting attrition.

Methods: The Kids' HELP trial examined the effects of Parent Mentors on insuring uninsured minority children. We tested a retention strategic framework consisting of: 1) optimizing cultural/linguistic competency; 2) staff training on participant relationships and trust; 3) comprehensive participant contact information; 4) an electronic tracking database; 5) reminders for upcoming outcomes-assessment appointments; 6) frequent, sustained contact attempts for non-respondents; 7) financial incentives; 8) individualized rapid-cycle quality-improvement approaches to non-respondents; 9) reinforcing study importance; and 10) home assessment visits. We compared attrition in Kids' HELP vs. two previous RCTs in similar populations, and conducted bivariate and multivariable analyses of factors associated with Kids' HELP attrition.

Results: Attrition in Kids' HELP was lower than in two similar RCTs, at 10.9% vs. 37% and 40% ($P < 0.001$). After multivariable adjustment, missing the first outcomes follow-up assessment was the only factor significantly associated with attrition (relative risk = 1.5; 95% confidence interval, 1.1–2.0).

Conclusions: A retention strategic framework was successful in minimizing attrition in minority, low-income children. Participants missing first assessment appointments were at highest risk of subsequent attrition. These findings suggest that deploying this framework may help RCT retention of low-income minority children, particularly those at the highest risk of subsequent attrition.

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1. Introduction

The recruitment and retention of racial/ethnic minority participants in clinical trials continue to be major challenges across a wide variety of conditions and healthcare settings. Multiple recent studies document that minority clinical-trial candidates are significantly less likely than whites to be approached about study participation and to be enrolled in clinical studies, including trials in the emergency department, for HIV/AIDS patients, for cancer

Abbreviations: CHIP, Children's Health Insurance Program; Kids' HELP, Kids' Health insurance by Educating Lots of Parents; RCT, randomized, controlled trial.

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patients, and in the evaluation of new molecular-entity drugs and biological products [1–4]. Although fewer studies have been conducted on racial/ethnic differences in participant retention in clinical trials, the evidence shows that retention rates in trials are significantly lower for minorities and those who speak a language other than English at home [5–7]. A recent review of childhood obesity studies also revealed that mean retention rates were lower in trials solely targeting Latinos and African-Americans [8].

Echoing these well-documented challenges in the literature of retention of minority children and their parents in clinical trials, two randomized, controlled trials (RCTs) by our team had attrition rates of 37–40% [9,10]. Prompted by these experiences and a review of the literature revealing that not enough is known about effective methods for minimizing attrition in minority children in clinical trials, our study aim was to develop, implement, and evaluate an innovative approach for achieving high retention rates in an RCT of an intervention targeting low-income minority children and their families. An additional goal was to identify child or caregiver characteristics at baseline associated with attrition at one-year follow-up of outcomes.

2. Methods

2.1. Strategic framework

Based on lessons learned from our team's prior RCTs targeting low-income, minority children [9,10], a strategic framework was developed to maximize retention in an RCT of the effects of Parent Mentors on insuring uninsured minority children called Kids' HELP (Kids' Health insurance by Educating Lots of Parents) [11]. The strategies in this framework were as follows:

- **Optimize cultural and linguistic competency.** The Kids' HELP trial target population was Latino and African-American uninsured children and their parents. To optimize cultural and linguistic competency throughout the trial, the four research staff hired for the trial were all bilingual Latinos or African-Americans, including a bilingual Latino research assistant responsible for assessing outcomes. This strategy was aimed at eliminating potential cultural and linguistic barriers to trial retention.
- **Research-staff training emphasized building participant relationships and trust.** It was theorized that participants would be less likely to dropout or be lost to follow-up if they had trusting relationships with staff.
- **Comprehensive contact information for participants and their relatives, friends, and neighbors.** Our prior experiences revealed that having only one telephone number for a participant increases the risk of dropout or loss to follow-up. To ensure multiple alternatives in the event of an initial failure to contact a participant, we collected mobile, landline, and work telephone numbers for participant caregivers, along with e-mail and postal addresses, if available. We also requested similar complete contact information for at least one relative and one friend or neighbor for each participant.
- **Electronic tracking database.** A detailed electronic tracking database was created to monitor study outcomes, adherence to monthly outcome phone calls, and participants at risk for loss to follow-up or currently lost to follow-up. The database also included the number of contact attempts, the mode of contact (telephone, text, e-mail, letter, or fax) of all contact attempts, and upcoming outcomes-assessment appointments with participants.
- **Reminders for upcoming outcomes-assessment appointments.** Participants were reminded about upcoming appointments

for outcomes assessments with research staff via telephone messages, texts, and/or e-mails.

- **Frequent, sustained contact attempts for non-respondents.** For any participant who did not respond to a scheduled outcomes follow-up assessment, the outcomes researcher contacted the participant daily, varying the time of day for the subsequent contacts, as well as the modes of communication (mobile and landline telephones, texts, e-mails, and certified letters), and continued such contacts periodically until a response was obtained or the study ceased.
- **Incentives for every survey completed.** To compensate participants for their time and effort and incentivize them to complete all follow-up surveys, honoraria of \$50 at enrollment, \$5 for monthly follow-ups, and \$10 for six- and 12-month surveys were provided.
- **Individualized rapid-cycle quality-improvement approach to non-respondents.** In weekly research-team meeting, all non-respondents were identified and discussed using an individualized rapid-cycle quality-improvement framework. Team members most familiar with the non-responding participant shared potential root causes for the non-response. The team then developed and implemented an action plan, evaluated the outcome at the next team meeting, and continued or modified the action plan, based on the results. Action plans included varying daily time of the phone call; using alternative phone numbers; contacting family members, friends, or neighbors; text messages; mailing a certified letter; having the recruitment research assistant who made the first contact with the participant reach out to the participant; leaving a voice mail about the importance of the study and participation; and making a home visit.
- **Reinforce the importance of the study.** In scheduling follow-up appointments and voice messages left for non-respondents, a script was developed which emphasized why the study was so important for children, families, and the community, and that participation would help us to insure more children and improve children's health, healthcare, and well-being.
- **Home visits as a last resort.** When repeated contacts using all other means were exhausted, research staff made one or more home visits to non-responding participants and their families. When families were not at home, a note regarding the importance of completing the follow-up was left, along with the business card of that particular research-team member.

2.2. Summary of design and methods of Kids' HELP trial

The Kids' HELP trial was the first RCT of the effectiveness and cost effectiveness of Parent Mentors (PMs) in insuring uninsured minority children [11]. PMs were experienced parents with at least one child covered by Medicaid or CHIP who received two days of training, then assisted families for one year with insurance applications, retaining coverage, medical and dental homes, and social determinants of health. Controls received traditional state Medicaid/CHIP outreach and enrollment efforts. The primary outcome was obtaining health insurance one year after enrollment. The PM intervention was more effective than traditional outreach/enrollment in insuring uninsured minority children [12]. The PM intervention also insured children faster, and was more effective in renewing coverage, improving access to medical and dental care, reducing out-of-pocket costs, achieving parental satisfaction and quality of care, and sustaining insurance after intervention cessation, and saved \$6,045.22 per child insured per year [12]. Complete details on the design, methods, and results of the Kids' HELP trial

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